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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,423	03/26/2004	Tenneille E. Ludwig	960296.00050	2623

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,423	LUDWIG ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-7,10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/04, 8/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending. Applicant should note that the examiner for this application has changed.

Election/Restrictions

Applicant's election with traverse of Group III, claims 8 and 9, in the reply filed on 8/22/06 is acknowledged. The traversal is on the ground(s) that searching all four distinct inventions would not be burdensome to the examiner, since Groups I-IV regard related subject matter (Reply, page 4, paragraph 3). This is not found persuasive because burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Searching the instant four patentably distinct inventions would, in fact, impose a serious burden on the examiner. If applicants admit on the record that Groups I-IV are obvious over one another, the Groups will be rejoined, since a single search would suffice for all Groups. By so admitting, applicants stipulate that if a reference is considered prior art over one Group, it shall be considered prior art over all four Groups.

Furthermore, whether the subject matter of the Groups is "inextricably linked" or not is not at issue in U.S. restriction practice. Inventions must be unified by a single concept under EPO/WIPO restriction practice; in the United States, all that is required is that the inventions be independent and/or distinct. Applicant has not pointed out any

supposed errors in the restriction requirement or provided any arguments as to the four inventions' not being distinct.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-7, 10, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/22/06. Examination will commence at this time on claims 8, 9, and 12 ONLY.

Specification

The use of the trademark "KNOCK-OUT" has been noted in this application (paragraph 16). It should be capitalized wherever it appears **and be accompanied by the generic terminology.** The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931), and M.P.E.P. § 608.01(v)(I).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is drawn to "a stem cell culture" comprising various components, including a culture plate, a nutrient medium, and stem cells; the claim appears to be drawn to a composition. However, line 3 of claim 8 recites a method step ("wherein the cells **are cultured** in the medium"). A single claim that claims both a product or apparatus and the method steps of using said product or apparatus is indefinite under 35 U.S.C. § 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. § 112, second paragraph. See M.P.E.P. § 2173.05(p). In this case, it is not clear whether the claim is drawn to a composition comprising a plate, a medium, and cells, or to a process for using the same. Clarification is required. In the interest of compact prosecution, the claim is interpreted as being drawn to a composition comprising a culture plate; a nutrient medium therein, said medium having an osmolarity in excess of 330 mOsm; and human embryonic stem cells in said medium.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (2002, U.S. Patent Application Publication 2002/0076747; reference A). The claims are interpreted as being drawn to a composition comprising a culture plate; a nutrient medium therein, said medium having an osmolarity in excess of 330 mOsm; and human embryonic stem cells in said medium. In some dependent claims, the medium has an osmolarity of about 350mOsm. In some dependent claims, the cell is undifferentiated.

Price et al. teach a composition comprising a culture plate; a nutrient medium (paragraph 128) therein; and mouse embryonic stem cells (ES-D3 cells) (Example 1, paragraphs 129-133). Price et al. do not exemplify a composition comprising nutrient

medium of 330 or 350mOsm or a composition comprising human ES cells. Price et al. do teach, however, that the osmolarity of the medium may be "as high as about 350mOsm" (paragraph 101) and that said medium may be used to culture human ES cells (paragraph 102).

The selection of osmolarity of the medium of Price et al. would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Price et al. teach that the osmolarity may be up to about 350mOsm. The selection of the source of ES cells in the Example of Price et al. would also have been a routine matter of optimization on the part of the skilled artisan, said artisan recognizing that Price et al. teach that ES cells may be obtained from humans and cultured in the medium of their invention. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

/LEB/